

**U.S. SENATE
COMMITTEE ON SMALL BUSINESS &
ENTREPRENEURSHIP**

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Performing Arts Building
Ybor City Campus, Hillsborough Community College
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Hearing: Keeping Small Premium Cigar Businesses Rolling

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Summary

- Cigarette smoking is associated with high risks for cancers, circulatory diseases and emphysema. Every year, nearly 500,000 adults die from smoking-related diseases. For the past 50 years, the American cancer “epidemic” has primarily consisted of one disease, cancer of the lung, owing to one dominant lifestyle factor – cigarette smoking.
- Compared with cigarette smoking, prevalence of cigar use is much lower; in 2014 0.7% of Americans smoked premium cigars and 3.4% smoked machine-made products.
- Compared with cigarettes, other tobacco products are associated with considerably lower health risks. Smoke-free tobacco products are vastly less hazardous than combustible products. Among combustible products, epidemiologic studies document that cigar smoking is much less hazardous than cigarette smoking.
- A recent FDA study found that consumption of up to two cigars per day, while not completely safe, is neither associated with significantly increased risks for death from all causes, smoking-related cancers, coronary heart disease, stroke, or emphysema.
- With low prevalence and minimal to no adverse health effects, regulation of cigars will have negligible impact on public health.
- FDA’s unscientific conflation of cigarette smoking with smokeless tobacco use, vaping, cigar and pipe smoking falsely informs consumers that all tobacco products are equally deadly. This posture wastes government resources, undermines public health and does nothing to address the deaths caused by cigarette smoking.

I was trained as an oral and maxillofacial pathologist 40 years ago. By the early 1990's, I had been on the staff of the Comprehensive Cancer Center at the University of Alabama at Birmingham for 10 years. At this large academic medical center, I watched countless patients succumb to cancers and other diseases caused by cigarette smoking. I had been educated to believe that all tobacco products were equally hazardous. However, my experience providing pathologic diagnoses for hundreds of mouth cancers did not sync with what I had been taught. The vast majority of the patients I diagnosed were cigarette smokers and/or heavy drinkers. Virtually none of them had used moist snuff or chewing tobacco, despite the fact that these products were commonly used in the deep South.

I resolved the discrepancy by conducting research, resulting in the publication of 70 articles in peer-reviewed medical journals (1). I documented that, compared with cigarette smoking, smokeless tobacco use is 98% less hazardous, even for mouth cancer. In fact, a large recent study from federal and federally-funded investigators found that men who dipped or chewed tobacco had no excess risk for that disease (2). In addition, an American Cancer Society report on the top causes of 660,000 cases of cancer in the U.S. (3) ranked cigarette smoking #1, while smokeless tobacco did not even make the list.

The principal takeaway here is that all tobacco products do not have the same health risks. This also applies to combustible products like cigars, according to research from FDA officials (4).

Cigar Smokers

The cigar category encompasses a diverse spectrum of products. On one end are premium cigars that are hand-rolled by craftsmen; the rest of the category consists of machine-made, mass-produced cigarillos, little cigars and filtered cigars, sold in packs of various quantities.

Using nationally representative survey data, FDA investigators have distinguished between premium cigar smokers and those smoking mass-produced products (5,6). They estimated that 0.7% of Americans smoked premium cigars and 3.4% smoked machine-made cigars in 2014 (5). Smokers of premium products make up only 14-20% of all cigar users (5,6). Furthermore, only 7% of premium cigar smokers are daily users, compared with daily use by 22-37% of smokers of mass-produced products. Premium cigar smokers light up less than 2 days per month, and only 30% also smoke cigarettes. In contrast, mass-produced cigar smokers light up 1-2 weeks each month, and 58-66% smoke cigarettes. (5)

In another study FDA staff differentiated primary cigar smokers, who never smoked cigarettes, from two other groups: secondary cigar smokers who are former smokers, and dual users of both cigars and cigarettes (7). In that study, primary cigar smokers made up just over 40% of the 462 cigar smokers, while the other two groups comprised almost 60%. This is important because extensive cigarette use by the latter two groups, compounded by the likelihood that they smoke more and inhale more, likely raises their

health risks. Although this FDA study did not precisely describe smoking patterns, primary cigar smokers use fewer products (average 1.5 cigars on days smoked) and smoked fewer days, compared with secondary and dual users.

Health Effects of Cigar Smoking

The vast majority of cigar smokers are men (5), so it is best to focus only on men when discussing epidemiologic studies.

Usage patterns are important as we look at the health effects of cigar smoking. First, some basic principles. When you burn tobacco and inhale smoke, you consume nicotine and about 7,000 other chemicals. A 20- to 30-year career involving 10 deep puffs per cigarette and 20 to 40 cigarettes per day builds high risks for cancers, circulatory diseases and emphysema. The risks of cigarette smoking are proportional to the amount of smoke inhaled and the duration (years, decades) of exposure, and the death toll from cigarette smoking is high. Every year, 440,000 adults die from smoking-related diseases. For the past 50 years, the American cancer “epidemic” has primarily consisted of one disease, cancer of the lung, owing to one dominant lifestyle factor – cigarette smoking.

While cigar use involves burning tobacco, puffing on one or two cigars occasionally or even daily is not the same as deeply inhaling smoke from 20 or 30 cigarettes per day. One would therefore expect that cigar smokers, especially the primary group, would have lower health risks than cigarette smokers. That is in fact documented in a 2015 study authored by FDA staff (4).

For that report, FDA staff reviewed 22 epidemiologic studies on cigars and health outcomes, and they documented all causes of death and many smoking-related diseases. I will focus on the results for **men who are primary cigar smokers, that is, cigar smokers who had no history of cigarette use**. I will use the term relative risk (RR), which you can view as a multiplier. If a group of men who are cigar smokers has an RR=2 for a particular disease, it means they have twice the risk as the referent group of nonusers. An RR=1 is no risk at all. All RRs are accompanied by a 95% confidence interval, which is the generally accepted measure of statistical significance for epidemiologic results. If that range includes 1.0, the result is considered not statistically significant.

To start, let’s look at mortality for all causes of death. The first column of Table 1 shows that cigar smokers generally have elevated risks. While most studies do not report the number of daily cigars consumed, two studies (Kahn and Shanks) do. Those results are seen in the second column. Smoking one to two cigars per day had minimal to no risks.

Similar results are seen in the FDA study for various diseases related to smoking, including cancers, heart and circulatory diseases and emphysema. Table 2 shows risks for cancer among smokers of one to two daily cigars. For stomach, pancreas and bladder, elevated risks are minimal and/or based on very limited data. While some risk estimates are elevated, especially for parts of the body in contact with smoke, such as mouth/throat,

esophagus, larynx and lung, none are statistically significant. The risks for larynx cancer are based on only two deaths in the Shanks study and one death in the Shapiro study, which is why the confidence interval indicates that they are not reliable.

Table 3 contains the FDA results regarding cigar-related circulatory disease and emphysema for men who smoke one or two cigars a day. **There were no significantly elevated risks for death from coronary heart disease, stroke or emphysema, which are three big killers of cigarette smokers.** Aortic aneurysm – a bulge in the heart’s main artery – was the only disease that was elevated in men who smoke 1-2 daily cigars. It is a serious disorder but a distinctly uncommon cause of death; the mortality rate due to aortic aneurysm among those 45 and older dropped precipitously from 16 deaths per 100,000 in 2000 to 7.4 in 2014.

A follow-up mortality study of 1,139 current cigar smokers, as well as 1,177 pipe smokers, identified in U.S. Census Bureau surveys in 1985 and 1992-2011 was published by FDA staff last year (8). They divided cigar and pipe smokers into daily and non-daily groups. The results, summarized in Table 4, show that some diseases were elevated in daily cigar smokers. However, the Census Bureau surveys did not collect information on number of cigars smoked, so it is likely that the higher risks were among secondary cigar smokers and dual users who are more likely to smoke little cigars and cigarettes in higher quantities. Importantly, nondaily cigar users, who are more likely to smoke premium cigars, had no elevated risks.

The Takeaway Message for Cigar Smokers

Puffing or inhaling the smoke of burning tobacco is not without risk.

The FDA, which now regulates tobacco products, seems inclined to treat cigars the same as cigarettes. FDA staff wrote in their cigar study that “...cigar smoking carries many of the same health risks as cigarette smoking... We have observed that some risks associated with cigar smoking can be as high or higher than those associated with cigarette smoking, especially at the highest doses and levels of inhalation for cigar smoking.”

All tobacco consumers in the U.S. deserve truthful information and guidance. The sweeping FDA indictment ignores scientific evidence and misleads cigar smokers. It also ignores the important epidemiology principle that the level of risk is related to the level of exposure. In other words, harm is based on (1) how many people smoke; (2) how frequently and how many products are smoked; (3) the degree to which smoke is puffed and/or deeply inhaled. The following facts are indisputable with respect to cigars: (1) the prevalence of cigar use in the U.S. is extremely small, especially for premium cigars; (2) these products, especially premium category, are used infrequently and in small numbers; (3) they are puffed, rather than inhaled.

The agency’s unsupported position has led to needlessly subjecting cigar and pipe smokers, and the manufacturers of those products, to the same onerous and burdensome regulatory regime as much more hazardous cigarettes. Low prevalence, infrequent use

and reduced exposure translates into minimal harm at the population level. Epidemiologic analysis from FDA staff indicate that **consumption of up to two cigars per day, while not completely safe, is neither associated with significantly increased risks for death from all causes, nor smoking-related cancers.**

When Congress gave the FDA regulatory authority over tobacco products in 2009, it did not require that the agency treat all tobacco products as equally hazardous. Unfortunately, the FDA's regulatory actions have done just that, despite numerous scientific studies demonstrating that the risks from smoke-free tobacco (smokeless tobacco and e-cigarettes) are a tiny fraction of the risks of cigarette smoking, and despite the FDA's own study demonstrating that the risks of moderate cigar smoking are significantly lower than cigarette smoking.

The FDA's unscientific conflation of cigarette smoking with smokeless tobacco use, vaping, cigar and pipe smoking falsely informs consumers that all tobacco products are equally deadly. For all products other than cigarettes, the number of users is low, the adverse health effects are uncommon, rare or nonexistent. Thus, the impact of strict FDA regulation of these products will be inconsequential. The FDA's current posture wastes government resources, undermines public health and does nothing to address the 500,000 annual deaths caused by cigarette smoking.

Table 1. Relative Risk, RR (95% Confidence Interval) For All-Cause Mortality Among Men Primary Cigar Smokers

Study, year	All Cigar Smokers	Cigars per day	
Best, 1966	1.06 (0.92 – 1.22)		
Kahn, 1966	1.10 (1.05 – 1.16)	<5	1.04 (0.98 – 1.11)
		5-8	1.17 (1.06 – 1.29)
		8+	1.49 (1.24 – 1.77)
Cole, 1974	1.15 (0.70 – 1.90)		
Carstensen, 1987	1.39 (1.16 – 1.65)		
Lange, 1992	1.60 (1.30 – 2.00)		
Ben-Schlomo, 1994	0.48 (0.25 – 0.93)		
Shanks, 1998	1.08 (1.05 – 1.12)	1-2	1.02 (0.97 – 1.07)
		3-4	1.08 (1.02 – 1.15)
		5+	1.17 (1.10 – 1.24)

Bold indicates statistically significant elevation compared to never smokers.

Table 2. Relative Risks (95% CI) for Mortality From Cancers Among Men Smoking 1 or 2 Cigars Per Day

Cancer	Shanks, 1998	Shapiro, 2000	Other Studies
Mouth/throat	2.12 (0.43 – 6.18)	0	
Esophagus	2.28 (0.74 – 5.33)	1.80 (0.60 – 5.00)	
Stomach			1.68 (0.95 – 2.97) ¹
Pancreas	1.18 (0.69 – 1.89)	0.60 (0.30 – 1.40)	
Larynx	6.45 (0.72 – 23.3)	6.00 (0.70 – 53.5)	
Lung	0.90 (0.54 – 1.66)	1.30 (0.70 – 2.40)	1.14 (0.59 – 2.00) ²
Bladder	0.78 (0.29 – 1.71)	0	

¹ Jacobs 1999, 1 cigar per day.

² Kahn 1966, fewer than 5 cigars per day.

Table 3. Relative Risks for Mortality From Circulatory Diseases and Emphysema Among Men Who Smoke 1 or 2 Cigars Per Day

Disease	Shanks, 1998	Other Studies
Coronary heart disease	0.98 (0.91 – 1.07)	1.00 (0.90 – 1.10) ¹ 1.18 (0.76 – 1.82) ²
Stroke	1.01 (0.88 – 1.17)	
Aortic aneurysm	1.82 (1.11 – 2.81)	
Emphysema	1.39 (0.74 – 2.38)	

¹Kahn 1966, fewer than 5 cigars per day.

²Jacobs 1999, 1 cigar per day.

Bold indicates statistically significant elevation compared to never smokers.

Table 4. Relative Risks for Mortality Among Daily and Nondaily Exclusive Cigar Smokers¹

Disease	Daily	Nondaily
All Causes	1.22 (1.04 – 1.44)	1.12 (0.82 – 1.53)
Smoking-related cancers	1.80 (1.20 – 2.69)	1.08 (0.45 – 2.61)
Lung cancer	4.18 (2.34 – 7.46)	0.74 (0.08 – 7.26)
Cardiovascular diseases	1.12 (0.83 – 1.52)	1.20 (0.67 – 2.15)*
Respiratory diseases	1.86 (0.94 – 3.68)*	0
Emphysema	3.29 (1.33 – 8.17)*	0

¹ Christensen, 2018.

* Based in fewer than 10 deaths.

Bold indicates statistically significant elevation compared to never smokers.

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